UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,337	12/19/2001	Stefan L. J. Masure	JAB-1512	1691

7590 02/15/2005

Philip S Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,337	MASURE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-91* is/are pending in the application.

4a) Of the above claim(s) *50-55,57-63,65-67,69 and 71-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56,64,68 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *50-91* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12/19/01* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *892 references.*

DETAILED ACTION

Priority

1. It is suggested that the first sentence of the specification be amended to "This application is the National Stage of International Application No. PCT/EP00/04918, filed May 26, 2000"....

Sequence Compliance

2. The reply filed on 12/10/04 is not fully responsive to the previous requirement for compliance with the Sequence Rules, because the appropriate SEQ ID NOs are not recited in Figure 2 on page 6 of the specification. Appropriate correction is required, in order to be fully responsive to this Office action.

Information Disclosure Statement

3. The information disclosure statement filed 12/19/01 fails to comply with 37 CFR 1.98(a)(2), which requires a *legible copy* of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and *all other information or that portion which caused it to be listed.* It has been placed in the application file, but the information referred to therein has not been considered for those references crossed-out. Thus, those citations crossed-out will not be printed on the face of the patent issuing from this application.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

Election/Restriction

4. Applicant's election with traverse of Group II b (i.e., new claims 56, 64, 68 & 70; as it relates to SEQ ID NO: 9 (which further is a restriction/lack of unity requirement, and not a "species" election) in the reply filed on 12/10/04 is acknowledged. The traversal is on the ground(s) that "the individual groups are believed to be so related as to share common subject matter", and "[t]he division of the subject matter of the claims is believed to place an unreasonable burden on Applicants", since "a single unified search of the subject matter of the Claims centered about the subject matter of the elected species, necessarily extending into most of the other claims" . This is not found persuasive because the claims are directed to different products or to methods with different goals that further require different starting materials and possess different method steps; thereby, being distinct, as illustrated by the different classifications each of these different inventions possess. Additionally, as previously made of record and in contrast to Applicants' assertions, because the receptor member (GFRα-4) of original claim 1 is not novel (e.g., see PTO 409, and the Incyte ESTs on pg. 28), no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Again, note that PCT Rule 13 does not provide for multiple products or methods within a single application. Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 50-55, 57-63, 65-67, 69 & 71-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no

allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/10/04.

This application contains claims 50-55, 57-63, 65-67, 69 & 71-91 (and claims that recite nonelected SEQ ID NOs) that are drawn to an invention nonelected with traverse in Paper No. 12/10/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 U.S.C. § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 56 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, the current recitation of "a GFR α-4 receptor..." encompasses all naturally occurring GFR polypeptides; thereby, not involving the hand of man to isolate or purify the polypeptide receptor. It is suggested that amending the claims to "an isolated and purified GFR α-4 receptor..." should obviate this rejection.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 56, 64, 68 & 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification describes the rat GFR α-4 receptor molecule of SEQ ID NOs: 9 & 8. Page 5 of the specification then states that the claimed *mammalian* GDNF family receptor molecule of the present invention "is preferably from rat, mouse or human". However, pages 5–6 only describe the rat GFR α-4 receptor. Therefore, no written description of any different GFR α-4 receptor molecules from human or mouse, or from any other mammalian species, is described or known in the art at the time of filing Applicants' invention. Likewise, no generic or allelic variants, etc. that putatively hybridize to SEQ ID NOs: 1-7 (i.e., as it relates to claim 50) are described by nucleotide or amino acid sequence within the instant specification by which the skilled artisan could reasonably visualize what constitutes the claimed mammalian GFR α-4 receptor genus at the time of filing Applicants' application. Thus, the written description requirements under 35 U.S.C. 112, first paragraph, are clearly not met by the current claims, because a single species does not reasonably constitute a genus, as claimed.

It is suggested that amending the claims to an isolated GFR α-4 receptor polypeptide comprising or consisting of SEQ ID NO: 9 should obviate this particular rejection. See MPEP 2163.

7. Claims 56, 64, 68 & 70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific rat GFR α-4 receptor polypeptide consisting of SEQ ID NO: 9, does not reasonably provide enablement for any structurally and functionally uncharacterized polypeptide molecules or "functional equivalents", "bioprecursor", etc. thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The name "GFR α-4 receptor, or "functional equivalent or bioprecursor of said receptor" thereof", which encompasses random "substitution[s], deletion[s] and/ addition[s]"thereof, or comprises a fragment thereof, etc. (e.g., as defined on pages 7-8 of the specification) sets forth no structural and little functional characteristics. In contrast, the specification fails to define what critical amino acid residues constitute a biologically functional equivalent molecule, or bioprecursor, etc. "capable of binding persephin" (which is further not a recited claim limitation), as it relates to SEQ ID NO: 9. Nor does the instant specification teach how to distinguish any such randomly substituted, deleted, added or truncated polypeptide molecule/ biologically functional equivalent from any different polypeptide molecule that possesses none of the desired functions of the instant invention. In contrast, the skilled artisan would reasonably expect that any such random mutation, substitution, insertion, deletion, or truncation to the rat amino acid sequence of SEQ ID NO: 9 would result in an inactive polypeptide molecule. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence." Rudinger further states

on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study." Therefore, the lack of guidance provided in the specification, as to what minimal structural requirements are necessary for a functional polypeptide molecule, would prevent the skilled artisan from determining whether any random mutation/substitution/ insertion/deletion/truncation to the rat amino acid molecule of SEQ ID NO: 9 could be made that retains the desired function of the instant invention, because any such polypeptides would be expected to have adversely altered their biologically active 3-dimensional conformation without requiring undue experimentation to determine otherwise.

Lastly, in that no "*pharmaceutical* compositions" reasonably appear feasible for a receptor molecule that requires a cell membrane for any putative activity, claim 70 is not enabled because one skilled in the art would not reasonably know how to make and use such "pharmaceutical" compositions without requiring undue experimentation to discover such, and for the discussed above in the preceding paragraph; especially when it is unknown what disease state any such composition is envisioned to treat.

8. Claims 56, 64, 68 & 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 is dependent on a nonelected claim.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
February 09,2005

ROBERT C. HAYES, PH.D.
PATENT EXAMINER